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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,113	12/19/2001	Jaime E. Ramirez-Vick	25527-0001 C1	2617

25213 7590 03/08/2006

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,113	RAMIREZ-VICK, JAIME E.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-16-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2005 has been entered.

Preliminary Remark

All rejections and/or objections hereto not reiterated should be considered withdrawn in view of the Amendment received on August 22, 2005.

Claim Interpretation

Claims 2-4, 9-12, 15, 16, 20, and 21 recite the limitation, "surface of claim..." or "solid surface of claim ..." However, their base claims are drawn to a ligand-binding solid surface.

Since a solid support inherently has a surface, reference using the above phrase need not necessarily be referring to the "ligand-binding solid surface" containing all of its recited limitation.

While the above-mentioned limitations has been construed as referring to "ligand-binding solid surface" for prosecution, Applicants are encouraged to use consistent claim languages.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are indefinite for reciting the phrase, "a heterobifunctional spacer having at least two functional groups," because the term, "bifunctional" limits the functional groups to two (2) groups. However, the claims recite that the bifunctional spacer has "at least two functional groups" leaving open to more functional groups. This limitation appears to be inconsistent with the term, "heterobifuncational."

Claims 2-4 and 9-12 are indefinite by way of their dependency on claim 1.

Claims 6-8 and 13 are indefinite by way of their dependency on claim 5.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is the element which is responsible for the solid surface to be "ligand-binding."

In other words, claim 1 clearly recites that the claim is drawn to a ligand binding solid surface. However, the solid surface only comprises a heterobifunctional spacer having as one of its functional group, a soft base functional group. No other recitation is give as to how the solid support comprising said heterobifunctional spacer is able to bind a ligand.

Claims 2-4, 9, and 12 are indefinite by way of their dependency on claim 1.[1]

Claims 5-8 and 13-20 are also indefinite for the same issues as stated above.[2]

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[1] Claims 9 and 10, while dependent from the rejected base claim 1, recites the essential element, that is a "ligand" or "oligonucleotide" being comprised by the heterobifunctional spacer.

[2] Claim 21, while dependent from the rejected base claim 14, recites the essential element, that is an "oligonucleotide" being attached to the heterobifunctional spacer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al. (U.S. Patent No. 5,985,548, issued November 16, 1999, priority date under 102(e), February 13, 1995) in view of Tarlov et al. (U.S. Patent No. 5,942,397, issued August 24, 1999, filed December 10, 1997).

Collier et al. disclose a ligand-binding solid surface and its method of making comprising:

a) solid substrate (column 10, lines 47-50); and

b) a heterobifunctional spacer, wherein said heterobifunctional spacer is N-succinimidyl S-acetylthioacetate, which is a heterobifunctional cross linker agent that uses the primary amine reactive group, N-hydroxyl-succinimide (NHS) (column 11, lines 50-61). The heterobifunctional spacer comprises a thiol group (-SH), defined by the instant claim as being a soft-base (RSH). The artisans disclose that the NHS functional group of the heterobifunctional spacer reacted with amino-modified oligonucleotides so as to form the attachment thereto.

Collier et al. do not disclose that the instant heterobifunctional spacer is adsorbed onto a soft metal by soft-metal/soft-base interaction.

Tarlov et al. disclose a method of immobilizing biopolymers of solid surface comprising a gold substrate (column 3, line 21), or substrates that are metal such as silver, copper, platinum, palladium, ruthenium, and iridium (column 3, lines 22-23), wherein said substrate comprises an

organic linker which comprises an RSH functional group (column 44-46), wherein said organic linker comprises alkyl groups acting as a spacer, with an embodiment drawn to a hexamethylene linker which is about 10 carbon atoms in length.

Tarlov et al. disclose that the solid surface is employed in hybridization-based detection (column 1, lines 11-18), which involves immobilized oligonucleotides (Figure 4B; column 3, lines 51-54).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Collier et al. with the teachings of Tarlov et al., thereby arriving at the claimed invention for the following reasons.

Collier et al. disclose a method of immobilizing a ligand-binding molecule to a solid substrate, wherein the method involves the crosslinking of oligonucleotide probes to a heterobifunctional spacer comprising a reactive NHS group and a thiol group. While Collier et al. do not employ the method for the purpose of adsorbing the ligand-binding molecule to a solid substrate, such is demonstrated by Tarlov et al.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at producing the combination as Tarlov et al. already discloses a ligand-binding solid surface, wherein said ligand-binding solid surface is produced by adsorbing a heterobifunctional linker comprising an RSH group so as to adsorb the linker to a soft-metal substrate. While the heterobifunctional linker already had an oligonucleotide attached at its other end, given the teachings of Collier et al. who demonstrate that the attachment of oligonucleotides to a heterobifunctional linker comprising an NHS ester functional group is well known, would have expected a successful modification of the heterobifunctional linker of Tarlov et al. or that of Collier et al. so as to comprise an NHS ester functional group (with respect to the heterobifunctional inker

of Tarlov et al.);or adsorb the heterobifunctional linker to a soft metal surface via the functional SH group (with respect to Collier et al.) thereby arriving at the ligand-binding solid surface of the claimed invention.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

No claims are allowed.

Claims 1-13 are free of prior art as there is no prior art teaching or suggestion of employing a heterobifunctional spacer comprising two functional groups, one of the functional groups being succinimidyl-6-(biotinamido)hexanoate or succinimidyl 6-[6-(((iodoacetyl)amino)-hexanoyl)amino]hexanoate; and a solid surface comprising said heterobifunctional spacer or method of its use.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED,

so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
3/6/2006

YOUNG J. KIM
PATENT EXAMINER

yjk